REMARKS

I. Status of the Application

As originally filed, the Application presented claims 1-7 for examination. In response to an Office Action mailed April 17, 2000, which rejected all of the claims, Applicant amended claims 1 and 3 and added claims 8-20. A subsequent Final Office Action, which was mailed on February 9, 2001, maintained the rejection of claims 1-7, rejected newly added claims 8-10, and withdrew from consideration claims 11-20 as being drawn to a non-elected invention. Following the February 9, 2001 Final Office Action, Applicant filed an After Final Amendment, which was not entered. On May 7, 2001, Applicant filed a Continued Prosecution Application, together with a Preliminary Amendment that amended claim 1 and cancelled claims 8 and 9. An Office Action mailed on August 15, 2001, again rejected claims 1-7 and 10. Applicant filed a response on December 17, 2001, presenting arguments regarding patentability. A Final Office Action was mailed on April 16, 2002. Accordingly, claims 1-7 and 10 are under consideration in the present application.

Applicant submits that entry of the amendment is proper because it raises no new issues requiring a further search of the prior art and it places the claims in condition for allowance. Applicant therefore respectfully requests reconsideration of the pending claims in view of the above amendment and the following remarks.

By action taken here, Applicant in no way intends to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant expressly reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art.

II. Amendment of Claim 1

Applicant has amended claim 1 to clarify that the solidified matrix directly contacts that pharmaceutical agent, which has a "substantially crystalline particulate form." Applicant has also amended claim 1 to recite that the solidified matrix "consist[s] of one or more water-soluble polymers," which "enhance the dissolution rate of the pharmaceutical agent in water." In addition, Applicant has amended claim 1 so that it does not recite melting point. The specification, as filed, fully supports the changes to claim 1, and therefore Applicant submits that the amendment of claim 1 introduces no new matter. See, for example, Application at

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page 1, line 26-page 2, line 11; page 6, lines 23-32; page 8, line 1-page 9, line 20; page 12, Table 1, and lines 19-22.

III. Rejection of Claims Under 35 U.S.C. §§ 102(b), 103(a)

The Final Office Action rejected claims 1, 5, 7 and 10 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,480,654 to Tanaka et al ("the Tanaka '654 patent"), and rejected claims 1-7 and 10 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,478,852 to Olefsky et al. ("the Olefsky '852 patent") in view of the Tanaka '654 patent. Applicant submits that the Tanaka '654 patent and the 'Olefsky '852 patent, either alone or in combination, do not teach or suggest every limitation of claim 1, and therefore the cited references neither anticipate nor render obvious the claimed invention. Additionally, Applicant submits that nothing in the cited prior art, or in the knowledge generally available to one of ordinary skill in the art, suggests combining the Olefsky '852 patent and the Tanaka '654 patent to arrive at the claimed invention since, as discussed below, the Tanaka '654 patent teaches away from the claimed invention. Furthermore, modifying the Tanaka '654 patent in the manner described in the Final Office Action would impermissibly render the reference unsuitable for its intended purpose. Applicant therefore submits that claim 1, as well as claims 2-7 and 10, which depend on claim 1, are patentable over the prior art of record. Applicant respectfully requests withdrawal of the rejection.

The Olefsky '852 patent and the Tanaka '654 patent, when viewed alone or in combination, do not teach or suggest every limitation of claim 1 and therefore the references neither anticipate nor render obvious the claimed invention. Claim 1 recites a pharmaceutical dosage form, which comprises "a pharmaceutical agent and a solidified matrix." The pharmaceutical agent has a "substantially crystalline form" that is "at least partially coated with the solidified matrix to enhance the dissolution rate of the pharmaceutical agent in water." As indicated above, the present amendment clarifies that the solidified matrix "consist[s] of one or more water soluble polymers," which "directly contact[s] the pharmaceutical agent."

Applicant submits that neither the Tanaka '654 patent nor the Olefsky '852 patent discloses a solidified matrix consisting of one or more water-soluble polymers that at least partially coat and directly contact the crystalline particulate pharmaceutical agent. Instead, the Tanaka '654 patent discloses a dosage form that is "prepared by forming a coating layer on powder of a medicinal agent." Tanaka '654 patent at col. 2, lines 25-27. The coating layer

is a "water-insoluble material" that is formed "on the surface of medicinal particles before granulation," and which "does not dissolve in water and gastric juice." Tanaka '654 patent at col. 2, lines 41-45, 60-62 (emphasis added). Hence, whereas the pharmaceutical agent recited in claim 1 directly contacts one or more water-soluble polymers, the medicinal agent disclosed in the Tanaka '654 patent contacts a water-insoluble material. Although the Final Office Action asserts that the Tanaka '654 patent discloses "adding a water-soluble polymer material," such material is added only after the medicinal agent has been coated with the water-insoluble material—i.e., during granulation or tableting. See Tanaka '654 patent at col. 2, lines 36-40. Thus, the water-soluble polymer disclosed in the Tanaka '654 patent does not directly contact the medicinal agent since the medicinal agent includes a coating of a water-insoluble polymer material.

According to the Final Office Action, the Olefsky '852 patent discloses "solid form preparations." However, the reference does not disclose a solidified matrix, which consists of one or more waters soluble polymers that at least partially coat and directly contact the crystalline particulate pharmaceutical agent.

Applicant further submits that the Tanaka '654 patent and the Olefsky '852 patent do not disclose the use of a solidified matrix to enhance the dissolution rate of the pharmaceutical agent in water. Instead, the Tanaka '654 patent uses a pair of materials—a water-insoluble coating and a water-soluble polymer additive—to decrease the dissolution rate of the pharmaceutical agent. For instance, Example 1 of the Tanaka '654 patent describes the preparation of a "prolonged release dosage form," comprised of theophylline medicinal particles, which were first coated with a water-insoluble material (hydrogenated rape oil) and then combined with a blend of lactose and hydroxypropyl cellulose. Tanaka '654 patent at col. 4, lines 32-56. As can be seen in FIG. 1 of the Tanaka '654 patent, neat theophylline medicinal particles (curve a) exhibited the greatest rate of dissolution, whereas the prolonged release dosage form prepared in Example 1 (curve f) exhibited the lowest rate of dissolution.

In addition, Applicant submits that it is improper to combine the Olefsky '852 patent and the Tanaka '654 patent because the Tanaka '654 patent teaches away from the present invention. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *See e.g., W.L. Gore & Associates, Inc., v. Garlock, Inc.*, 220 USPQ 303, 311 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984), *cited in Manual of Patent Examining Procedure* § 2141.02 (8th Ed., 2001). As noted

above, the Tanaka '654 patent teaches the use of a water-soluble polymer to decrease the dissolution rate of medicinal particles. In contrast, the pharmaceutical dosage form recited in claim 1 includes a solidified matrix composed of one or more water-soluble polymers to enhance the dissolution rate of the pharmaceutical agent. Since the teachings of the Tanaka '654 patent are contrary to the claimed invention, Applicant submits that the reference cannot be used to render obvious the claimed invention.

Finally, Applicant submits that it is improper to combine the Olefsky '852 patent and the Tanaka '654 patent because modifying the Tanaka '654 patent to arrive at the present invention would render the reference unsatisfactory for its intended purpose. If proposed modification would render the prior art invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordan*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984), *cited in Manual of Patent Examining Procedure* § 2143.01 (8th Ed. 2001). As noted above, the express purpose of the Tanaka '654 patent is to provide a prolonged release dosage form, which is prepared by first forming a coating layer on medicinal particles, followed by blending the coated medicinal particles with a water-soluble material. If, however, the medicinal particles were instead coated with a water-soluble polymer, as required by claim 1, the dosage form disclosed in the example would likely exhibit little, if any, decrease in dissolution rate, which is contrary to the express purpose of the Tanaka '654 patent.

Since the prior art of record neither anticipates nor renders obvious claim 1, Applicant submits that claims 2-7 and 10, which depend on claim 1, are patentable over the prior art of record.

IV. Conclusion

In view of the foregoing, Applicant respectfully submits that all pending claims are patentable over the prior art of record. If the Examiner has any questions, Applicant requests that the Examiner telephone the undersigned.

Applicant believes that any fees associated with the filing of the present amendment have been identified in a transmittal that may accompany this paper.

However, if any fees are required in connection with the filing of this paper, and such fees have not been identified in the accompanying transmittal, if any, please charge deposit account number 23-0455.

Respectfully submitted,

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Matthew J. Russo
Reg. No. 41,282
Warner-Lambert Company
2800 Plymouth Road
Ann Arbor, MI 48105
Tel: (734) 622-1747
Fax:(734) 622-1553
Customer No. 28880

ATTACHMENTS:
Version With Markings To Show Changes Made
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Three Times Amended) A solid particulate pharmaceutical dosage form suitable for oral delivery comprising a pharmaceutical agent and a solidified matrix, the pharmaceutical agent being sparingly water-soluble [pharmaceutical agent in] and having a substantially crystalline particulate form, [wherein said crystaline particulate] the pharmaceutical agent being [is] at least partially coated with the solidified matrix to enhance the dissolution rate of the pharmaceutical agent in water, the solidified matrix directly contacting the pharmaceutical agent and consisting of [a] one or more water-soluble [polymer] polymers [having a melting temperature less than that of the pharmaceutical agent].